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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/630,473

07/29/2003

Mark E. Deem

38349-0103H

9190

7590

06/16/2004

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EXAMINER

LEWIS, AARON J

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,473

Applicant(s)

DEEM ET AL.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-5 are are rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al. ('951).

As to claim 1, Alferness et al. disclose a method for lung volume reduction (see abstract and col.2, lines 28-30), said method comprising: deploying an obstructive device (70) in a lung passageway to a lung tissue segment (col.4, lines 13-25); and aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment (col.5, lines 18-20 and lines 26-30).

As to claim 2, Alferness et al. disclose method for lung volume reduction (see abstract and col.2, lines 28-30), said method comprising deploying a unidirectional valve

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within a lung passageway to a lung tissue segment (col.6, lines 56-65 and col.4, lines 13-25), wherein the valve opens during expiration to allow outflow of gas from the lung segment and the valve closes during inspiration to prevent inflow of gas to the lung segment.

As to claim 3, Alferness et al. disclose a method for lung volume reduction (see abstract and col.2, lines 28-30), said method comprising: accessing a lung passageway to a lung tissue segment (col.4, lines 13-25); and deploying a blockage device in the passageway (col.6, lines 56-65 and col.4, lines 13-25).

As to claim 4, Alferness et al. disclose a device (70) for obstructing and bleeding gas from a lung tissue segment (col.5, lines 18-20 and lines 26-30), said device comprising: an expandable structure (90) which is deployable within a lung passageway (col.5, lines 36-38 and lines 48-53); and means for the expandable structure for blocking airflow in one direction therethrough and permitting airflow in the other direction therethrough (col.6, lines 56-65 and col.4, lines 13-25).

As to claim 5, Alferness et al. disclose a system for obstructing a lung passageway to a lung tissue segment, said system comprising: an access catheter (70) having a proximal end, a distal end (figs.2,3), and at least one lumen (82) extending therethrough, and an obstruction device (90) deployable within the lung passageway having an inlet port adapted for aspirating the lung tissue segment through the inlet port, wherein the obstruction device is introduceable by the access catheter (col.6, lines 56-65 and col.4, lines 13-25).

***Claim Rejections - 35 USC § 103***

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al. ('951) in view of Daniel et al. ('455).

The difference between Alferness et al. and claim 6 is the incorporation of the obstruction device into a kit that also includes instructions for use according to a method of lung volume reduction.

Daniel et al. teach the incorporation of an obstruction device (e.g. endoscope) into a kit that also includes instructions for use (col.5, lines 30-38) for the purpose of providing medical personnel with both the equipment and instructions for performing surgical procedures within a patient's thoracic cavity using an endoscope.

It would have been obvious to modify the obstruction device of Alferness et al. to incorporate it into a kit and include instructions for performing surgical procedures because it would have provided medical personnel with both the equipment and instructions for performing surgical procedures within a patient's chest cavity as taught by Daniel et al..

Claims 7 and 8 are equivalent in scope to claim 6 and are included in Alferness et al. as modified by Daniel et al. for the reasons set forth above with respect to claim 6.

### ***Conclusion***

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5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant kits having endoscopes and instructions for performing surgical procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
June 14, 2004